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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/600,631 | 02/12/2001 | David Reginald Adams | 040283/0182 | 9046 |

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EXAMINER

ANDERSON, REBECCA L

ART UNIT

PAPER NUMBER

1626

DATE MAILED: 03/07/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/600,631

Applicant(s)

ADAMS ET AL.

Examiner

Rebecca L Anderson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 and 23-27 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-17 and 23-27 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Claims 1-17 and 23-27 are pending in the current application.

Specification

The statement, "This is a 371 of international application PCT/GB99/00223 with international filing date 01/22/1999 published in English" must be inserted as the first sentence of the specification.

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Claim Objections

Claims 11 and 17 are objected to because of formatting errors. The spacing between words varies and is inconsistent. New claims should be submitted with the correct spacing between words and punctuation.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-11 and 17 recite the limitations of substituents in R1. There is insufficient antecedent basis for this limitation in the claim since the base claim 1 defines R1 as only aryl. This rejection can be overcome by adding the limitation of "substituted or unsubstituted" to the definition of R1 in claim 1.

Claims 14-17 recite the limitations where R2 can be alkenyl, alkynyl, substituted alkyl, cyclic, etc. There is insufficient antecedent basis for these limitations in the claims. These claims depend on claim 1 where R2 can only be hydrogen or alkyl. This

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rejection can be overcome by adding these limitations as choices for R2 in the base claim 1.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 24 recites the broad recitation "treatment" and the claim also recites "prophylaxis" which is the narrower statement of the range/limitation. This rejection can be overcome by deleting "including prophylaxis" from the claim. Claim 25 recites the broad recitation "insomnia" and the claim also recites "travel insomnia and insomnia associated with terminal illness" which is the narrower statement of the range/limitation. This rejection can be overcome by deleting "including travel insomnia and insomnia associated with terminal illness" from the claim.

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In regards to claim 24, there is no support that applicant can prevent or "prophylaxis" all CNS disorders. As stated in the MPEP 2164.01 (a), "There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue."

In In re Wands, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have need described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

Therefore claim 24 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention with out undue experimentation. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with

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these claims. For example, CNS disorder therapy art remains highly unpredictable. The various types of CNS disorders have different causative agents, involve different cellular mechanisms, and, consequently, differ in preventive protocol. Therefore, based on the unpredictable nature of the invention and state of the prior art and the extreme breadth of the claims, one skilled in the art could not use the claimed invention without undue experimentation.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,2, and 23-27 are rejected under 35 U.S.C. 102(b) as being anticipated by GB 872447.

Claims 1 and 2 of the current application teach a compound of the formula (1) where R1 can be phenyl and R2 can be hydrogen. Claim 23 teaches a composition comprising the compound of formula (1). Claims 24-27 teach methods of treating CNS disorders and muscle relaxation.

GB 872447 discloses the pharmacologically active compound of 1-carbamyl-3-phenyl-azetidine in example 3 page 2 line 7 and claim 11 page 3 line 3. GB 872447 also discloses the use of the compounds of the formula on page 1, line 12 for use as sedatives and antispasmodic agents. The compounds in GB 872447 were also administered to rats to test its antispasmodic capabilities page 1, line 30. Therefore, it would have been anticipated by someone of ordinary skill in the art at the time of the invention to make the compound of formula (1), make a composition containing the

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compound of formula (1), and to use the compound of formula (1) as a treatment for CNS disorders and for muscle relaxation.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

In view of the above 102 rejection, claims 1-17 and 24-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over GB 872447 and EP 0 194 112.

Determining the scope and contents of the prior art

GB 872447 discloses the pharmacologically active compound, useful as a sedative and an antispasmodic agent, of 1-carbamyl-3-phenyl-azetidine in example 3 page 2 line 7 and claim 11 page 3 line 3. GB 872447 also discloses the use of the compounds of the formula on page 1, line 12 for use as sedatives and antispasmodic agents. The compounds in GB 872447 were also administered to rats to test its antispasmodic capabilities page 1, line 30. EP 0 194 112 discloses structurally related compounds of the formula I, column 1, line 40 wherein the aryl group at the 3rd position

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of the azetidine can be substituted with halogens, loweralkyl, trifluoromethyl, etc. column 1 lines 45-50, which are useful as anti-muscle tension and antispasmodic agents. EP 0 194 112 also discloses that the carboxamide can be substituted by hydrogen, cycloalkyl, and substituted and unsubstituted loweralkyl, etc. column 1 lines 53-60.

Ascertaining the differences between the prior art and the claims at issue

The claims at issue teach a pharmacologically active aryl azetidine compound of the formula (1) wherein R1 can be aryl and R2 can be hydrogen or alkyl. Claim 23 teaches a composition comprising the compound of formula (1). Claims 24-27 teach methods of treating CNS disorders and muscle relaxation. The difference between the claims at issue and the prior art of GB 872447 is that GB 872447 lacks substituents on the aryl group at the 3rd position of the azetidine and lacks substituents on the carboxamide.

Resolving the level of ordinary skill in the pertinent art

It would have been obvious to someone of ordinary skill in the art at the time of the invention to make and use compounds with a substituted carboxamide on the azetidine and a substituted aryl group in the 3 position of the azetidine when faced with the compounds of GB 872447 and especially when faced with the structurally related compounds of the secondary reference EP 0 194 112 which have a substituted aryl in the 3 position of the azetidine and also have a substituted carboxamide. The motivation would be to produce similar compounds pharmacologically active against CNS disorders and useful for muscle relaxation.

Conclusion

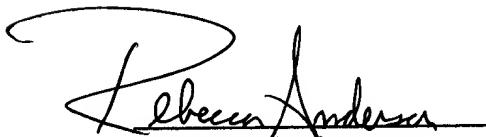
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Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rebecca L. Anderson whose telephone number is (703) 605-1157. Mrs. Anderson can normally be reached Monday through Friday 7:00AM to 3:30PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Joseph McKane, can be reached at (703) 308-4537.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone numbers are (703) 308-1235 and (703) 308-0196.

A facsimile center has been established. The hours of operation are Monday through Friday, 8:45AM to 4:45PM. The telecopier numbers for accessing the facsimile machine are (703) 308-4242, (703) 305-3592, and (703) 305-3014.



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